02b - STATEMENT OF WORK

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STATEMENT OF WORK

Please consult the definitions section at the end of this document for an explanation of terminology used in this solicitation.

I. GENERAL REQUIREMENTS

The Contractor shall be responsible for performing preanalytic processing, analysis, and result interpretation for clinical and anatomical pathology specimens as requested by Government Medical Treatment Facilities (MTF), VA Medical Centers (VAMC), clinics and/or other government healthcare access points. Services shall include the transportation of clinical laboratory specimens to the contractor's laboratory(ies) (including providing the shipping/pickup containers), the performance of analytical testing as defined by the Contractor's reference test manual, the reporting of analytical test results and consultative services as required to assimilate the full scope of its laboratory operations to the ordering facility

Services to be furnished under this contract shall be ordered by issuance of a task order by the ordering activity for results to be delivered to the site designated on the task order and in accordance with standards, clauses and provisions of this document.

The Contractor shall provide an Authorized FSS Price List pursuant to clause I-FSS-600 Contract Price Lists (located in Document 02 – Solicitation Document). The FSS Price List shall also include the following additional elements:

- **LOINC –** Logical Observation Identifier Names and Codes, if applicable
- **Specimen Collection And Handling Requirements –** Price list must indicate whether test demographic information is available upon request in either hardcopy or electronic format, listing any e-mail addresses or web links necessary to obtain the Requirements.
- **Turnaround Time (TAT) Table**, as proposed by the contractor in Document 04 – Vendor Response Document and agreed upon by the contract award (in lieu of #11 in I-FSS-600)
- **Hours of Operation**, as proposed by the contractor in Document 04 – Vendor Response Document and agreed upon by the contract award. This should detail the hours of operation upon which the turnaround times are based.
- **Use of Subcontractors** - If applicable, indicate the names of subcontractors and their testing site(s), as proposed in section (d) of Document 04b – Technical Proposal, Sub Factor B.1 (in lieu of #22 in I-FSS-600)

II. GENERAL QUALIFICATIONS

A. Licensing and Accreditation

Only fully licensed/accredited laboratories actively engaged in providing the specific services and laboratory testing outlined in this solicitation will be considered. The Contractor must continuously hold a Certificate of Compliance or Certificate of Accreditation from the Centers for Medicare and Medicaid Services as meeting the requirements of the Clinical Laboratory Improvement Amendments of 1988 or must demonstrate accreditation by a regulatory agency with deemed status from the Centers for Medicare and Medicaid Services, e.g. The College of American Pathologists, and/or other state regulatory agencies, as appropriate, and as

mandated by federal and state statues. The Contractor must maintain valid certifications throughout the performance period of this contract.

The Contractor shall provide a copy of all relevant permits/licenses and certifications inclusive of any sanctions current or pending throughout the United States of America prior to contract award. In addition, the Contractor shall be responsible for providing a written guarantee or evidence that all subcontractors have appropriate licensure and accreditation to perform tests that the primary contractor cannot perform prior to contract award. **Any proposed subcontractor changes during the contract performance period must have prior approval by the Contracting Officer (CO). Changes to the requirements will be executed by a bilateral modification to the contract**. **Each subcontractor must maintain the same certifications, accreditations, and Medical Malpractice Insurance as required of the Contractor (see Technical Proposal, Sub Factor B.1).**

Contractor policies and procedures shall comply with Health Insurance Portability and Accountability Act (HIPPA).

B. Documentation of Accreditation/Licensure

The Contractor shall maintain current accreditation and notify the Contracting Officer of any lapse in state license, CLIA certification, or clinical pathology certification. The Contractor shall provide a copy of the renewed licenses/certificates to the Contracting Officer before expiration. Immediate (within 24 hours) notification must be given to ordering activity upon adverse action by a regulatory agency.

C. Malpractice Liability Insurance

Malpractice liability insurance shall be by a commercial insurance company in the business of providing the required insurance coverage of not less than $1,000,000.00 per occurrence (see Clause 852.237-7 located in 02a – Solicitation Document). **The Contractor shall provide a copy of the Medical Malpractice Insurance Certificate before award of the contract.**

The Contractor shall notify the contracting officer in writing of any malpractice investigation or licensure or certification suspension which concerns the Contractor or any employees, within 24 hours of notification of an investigation or suspension.

Any Subcontractor performing under this contract must also have malpractice liability insurance in the amount of $1,000,000.00 per occurrence, and a copy of the Medical Malpractice Insurance Certificate must be provided before award/performance of the contract. Please also see Document 4b - Technical Proposal, Sub Factor B.1

III. CONTRACTOR'S RESPONSIBILITIES

A. Procedure Guidance

The Contractor shall make available either through its electronic catalog or upon request the following information:

- Specimen collection and handling requirements
- Test reference intervals adjusted for ages, sex, or race, when required
- Test specific sensitivity, specificity, and interferences, when required
- Result code (electronic transmissions only)

- Test critical values, if any
- Location of test performance by test name (i.e. name of primary laboratory, name of separate branch division of primary lab, name and address of secondary/subcontracted laboratory must be cited)

B. Sample Preparation

Each ordering activity will prepare (collect and handle) and package laboratory specimens in accordance with the requirements defined in the Contractor's commercial specimen collection guide. The packaging and transportation procedures must be of a quality that ensures the integrity of the specimen throughout the shipment process.

C. Supplies

The Contractor shall provide all necessary supplies for collecting, preserving, packaging, and transporting/shipping specimens normally provided to its commercial customers, not limited to the following:

- Forms
- Specimen containers
- Special media or culture tubes for samples
- Specimen preservatives
- Dry ice and appropriate container
- Shipping and packaging containers
- Specimen carriers
- Labels as required by transportation guidelines

If a medicolegal specimen is submitted, the Contractor shall provide its own special forms and special handling procedures to maintain valid **"chain of custody possession"** and develop the formal documentation necessary for that purpose. The Contractor's testing personnel that performed the analysis may be required to provide Court testimony. Contractor testimony shall be provided as required at no additional expense to the Government. If a specimen is required for medical-legal issues, at the request of the Government, the specimen shall be retained indefinitely.

The Contractor shall contact the COR within a maximum of five (5) calendar days after award of task order or Blanket Purchase Agreement, to coordinate the furnishing and delivery of specimen collection and transportation supplies, terminal or data fax and supplies, and the installation of equipment. The COR will request replenishment of supplies from the Contractor on an as needed basis.

D. Transportation Services

Proper tracking of specimen must be maintained from the initial pickup/shipping of the specimens from the ordering activity throughout the testing process at the Contractor's laboratory.

STAT/Emergency Pickup

The Contractor shall pick up STAT/emergency pick up services, when available, as consistent with the Contractor's commercial practices and within a time frame agreed upon at the task order level.

Routine Pickup

The Contractor shall provide routine scheduled specimen pickup as consistent with the Contractor's commercial practices and within a time frame agreed upon at the task order level. The ordering activity COR or designee shall notify the Contractor during weekends and Federal holidays, via telephone, if a pick-up courier is required.

E. Testing

The testing methodology and reference ranges for a test must be defined in the laboratory user manual. The Contractor shall advise facility of any changes in methodology, procedure, reference ranges and any new tests introduced no later than two weeks prior to test change implementation.

In the event that the Contractor discontinues and/or substitutes a new test, the Contractor shall notify the CO prior to the intended change. Any such change may be sufficient cause for changing to an alternate contractor for the assay(s) for the duration of the contract at the sole discretion of the CO.

All clinical reference laboratory testing shall be executed in accordance with standard industry practices. All test methods shall be FDA approved. Any non-FDA approved method being performed shall have a documented validation plan. Upon request the validation plan and validation results shall be made available.

F. Test Result Reporting

A report is defined as a final copy of laboratory testing results. This report shall be received by remote terminal where applicable. If results are previously telephoned, the report must include the name of the individual notified of the results. Each test report shall include all information as required by Regulatory Agency Requirements.

Contractor shall provide test results via one of the following methods:

1. Ground mail
2. Fax transmission
3. Access to the Contractor's computer system by the ordering facility, i.e. web-site, installation of software on the Government computer, installation of Contractor hardware with required software.
4. Inter-connectivity between Contractor computer system and Government computer system, i.e. results are automatically transmitted from the Contractor computer directly into the Government computer system without human intervention.

All completed and/or partial test results shall be reported to the ordering activity within awarded Turnaround Time (TAT), except where specified. Contractor shall provide all required hardware and software (including installation) and related consumable supplies to support the transmission of electronic data for each ordering activity at no additional charge (See listing of "All Inclusive FSS Price" in Document 05 – Commercial Sales Practice Format). Any necessary "additional required connections" shall be the responsibility of the contractor. All equipment, software and hardware remain the property of the contractor.

Contractor shall be responsible for preventive and as-needed maintenance on any installed fax and all peripheral devices; shall have the responsibility to train medical center personnel in routine operations (loading and unloading paper, ribbon changes, test and reset); and shall provide a validation service (fax or telephone) in the event of transmission or printer degradation, if requested by the ordering activity. **Additionally, contractor is responsible for**

transmission of all data to be accomplished in a manner that protects the privacy of all personally identifiable patient information

Critical Tests

The Contractor shall immediately telephone the respective COR, requesting Clinician or designee to report Critical Value or test result that may indicate a life threatening condition. Appropriate notification information will be provided at the time of task order award.

STAT/Emergency Tests

The Contractor shall provide test results to the ordering activity within the commercially published emergency Turnaround Time (TAT), unless otherwise agreed. The Contractor shall report all STAT and abnormal test results to ordering activity upon completion of testing.

Routine Tests

The Contractor shall provide routine test results to the ordering activity in accordance with the testing specifications defined in the Contractor's commercial specimen collection guide. Test procedures requiring a turnaround time longer than 24 hours (excluding the above exceptions) shall be identified by the Contractor before contract award and approved by the Contracting Officer.

Documentation

The Contractor shall ensure that all required documentation is, at a minimum, timely, legible, and accurate. Contract personnel shall indicate responsibility for the content and accuracy of all prepared and transcribed reports. The Contractor shall have a system in place to identify the personnel performing the test analysis.

G. Retention of Specimens

Upon completion of the testing, the Contractor shall retain all specimens as required by regulatory agencies.

H. Utilization Reports

The Contractor, upon request, shall provide to each ordering activity at a minimum, the utilization reports customarily provided to commercial customers. The report shall at minimum identify the test code, test name, YTD volumes, unit cost, YTD expenditures, and turnaround times.

IV. CUSTOMER SERVICE

The Contractor shall provide telephone number(s) and contact personnel to be used by the ordering activity to address questions regarding their commercial services. The Contractor shall include names and telephone numbers of technical directors and pathologists available for consultation.

The Contractor shall assign a specific local account representative to each ordering activity.

The Contractor shall provide preventive and as-needed maintenance and replacement, if necessary, on any contractor provided hardware at the facility/clinic at no additional charge to the Government. The Contractor shall provide maintenance within 72 hours of notification by the COR or designee.

In case of failure of the automated system, the Contractor shall provide an alternate route of transmission to the participating ordering facility or clinic.

V. CONTRACT QUALITY ASSURANCE/QUALITY CONTROL

The Contractor facilities, test methodologies (defined as the principle of the method), validation studies, and quality control information may be examined by representatives of the Government at any time during the life of the contract.

The Contractor shall comply with all applicable OSHA, Federal, State, laws, and regulations as required for performing the type of services required.

GENERAL DEFINITIONS FOR LABORATORY SERVICES

Contracting Officer (CO) – Individual(s) at the VA National Acquisition Center (NAC) authorized to enter into, administer, and/or terminate contracts and make related determinations and findings. The term includes certain authorized representatives of the contracting officer acting within the limits of their authority as delegated by the contracting officer.

Contracting Officer's Technical Representative – A Federal employee who assists the ordering/issuing agency contracting officer in the administration of task orders issued under this contract. The COTR is primarily responsible for the day-to-day program management of the ordering activity's task or task orders. Ordering agencies may have different designators for this category (e.g. GTR- Government Technical Representative, COR – Contracting Officer's Representative, etc.)

Critical Value - A test result that requires evaluation by a physician or other health care provider as soon as verified. Failure to take appropriate action as a result of a critical value might cause harm or undue suffering for a patient.

Reference Value - A range of test values expected for a designated normal population of individuals.

Routine Test - A test that is usually performed at high volume in which the result is required in 24 hours generally.

Special handling - Unusual circumstances may dictate the need for a specimen to be picked up specially, run out of sequence at a special time, or reported within a shorter than usual time.

Specialized Test - A test that is performed in low volume but the technology, expense, or time-consuming nature of each test, is such that some delay is expected. The delay usually occurs to allow tests received from different centers to be batched to make the operation cost-effective.

STAT - A designated category of tests that requires immediate processing to expedite results to physicians handling potentially life-threatening cases.

Turnaround Time (TAT) - The length of elapsed time between pick-up or dispatch of specimen from the government ordering activity's laboratory and the receipt of the completed printed report received by the government ordering activity's laboratory.. Exception: For STAT tests, the TAT shall begin at the time of notification by the ordering activity laboratory to the contractor that the specimen is ready for pick-up. These definitions apply whether the contractor or a subcontractor performs the test.